Siemens Healthcare GmbH, Henkestr. 127, 91052 Erlangen, Germany

To all users of the following products:

MAGNETOM Biograph mMR

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Customer Advisory Notice MR016/24/P

CUSTOMER ADVISORY NOTICE

Certain parameters in EPI sequence resulting in defects of the gradient coil in the Biograph mMR system

Dear customer,

This letter is to inform you of a (potential) issue associated with the following product: Biograph mMR.

When does this issue occur?

When certain parameters (echo spacings 0.50 ms; 0.51 ms, and 0.52 ms) are used in EPI (echo-planar imaging), sequences will excite high internal stress inside the gradient coil assembly. This may lead to cracks in the gradient coil.

What are the possible risks to health?

These cracks may lead to damage of the gradient coil (water leaks, cable breaks, etc). In rare cases, such a crack may cause a break in the internal wiring of the gradient coil. This can lead to arcing and ultimately to smoke emission.

What steps can the user take to avoid the possible risks associated with this issue?

Do not use echo spacings of 0.50 ms, 0.51 ms, or 0.52 ms in epi sequences. Be careful to check the echo spacing of the sequences before starting them. This applies to Siemens sequences but also to third-party sequences, e.g., from collaboration partners (C2P), and sequences programmed by the user. The echo spacing of the sequence can usually be checked on the Sequence > Part 1 tab card, see Figure 1, orange). The sequence abbreviations (see Figure 1, green) may be, e.g., epse, epfid, cmrr, etc. These sequences are most often applied for functional imaging studies of the brain, such as diffusion-weighted imaging of the brain. The echo spacing can, e.g., be modified by changing the bandwidth.

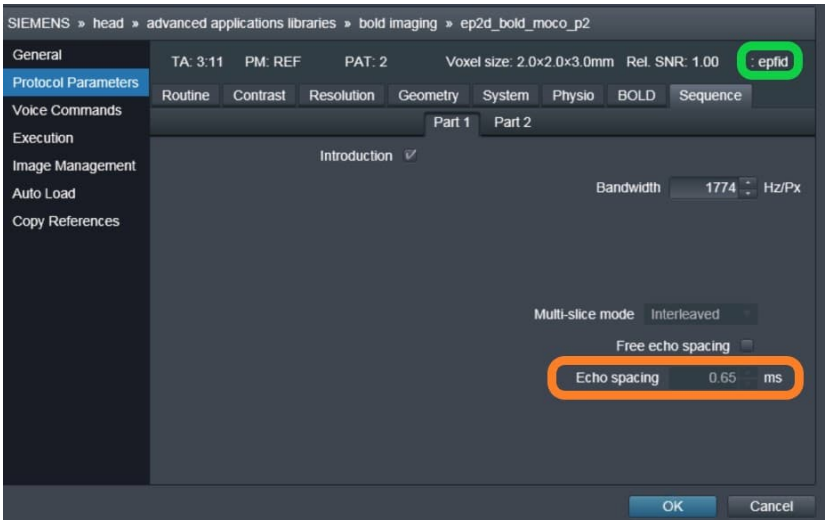

Figure 1: Example of a Sequence > Part 1 tab card for an epi sequence.

How will the issue finally be resolved?

Siemens Healthineers is preparing a software solution. This change will prevent the use of the critical parameter settings. The correction VE11P-SP08 (MR057/23/P) is planned to be available in CY Q3 2024.

Based on our investigation, you can continue to use your system if you avoid the above-mentioned parameter settings.

Dissemination of the content of this notice

Please ensure that all users of the affected products within your organization and others who may need to be informed receive the information provided with this notice and comply with the recommendations therein.

We appreciate your understanding and cooperation with this notice and ask you to immediately instruct your personnel accordingly. Please ensure that this notice is retained in your product-related records in an appropriate manner. Please retain this information at least until the measures have been finalized.

As applicable: Acknowledgement of Receipt of this Advisory Notice

Please fill out the attached Acknowledgment of Receipt and follow the instructions for sending it back to Siemens Healthineers.

What if you no longer have this device/equipment?

If this equipment is no longer in your possession, please forward this Advisory Notice to the new owner of this equipment. In such cases, please inform us about the new owner of the equipment.

The <relevant National Competent Authority> will be informed of this notice, if required.

We regret any inconvenience that this may cause and thank you in advance for your understanding.

Sincerely Yours
Siemens Healthcare GmbH

Electronically signed by: Steffen Schroeter
Reason: I have reviewed this document
Date: Feb 15, 2024 16:59 GMT+1

Steffen Schröter
Vice President of MR R&D
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Electronically signed by: Joerg Teiche
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